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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,875	06/18/2001	Lin-feng Chen	UCAL-234	1891

7590 06/06/2003
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EXAMINER

LEFFERS JR, GERALD G

ART UNIT	PAPER NUMBER
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1636

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DATE MAILED: 06/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/884,875	Applicant(s) CHEN ET AL.	
	Examiner Gerald G Leffers Jr.	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 19-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 19-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>8</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt is acknowledged of an amendment, filed 2/21/03 as Paper No. 9, in which claims 7 and 22 were amended. Claims 1-10 and 19-24 are pending in the instant application.

Any rejection of record in the previous office action, mailed 11/19/02 as Paper No. 7, not addressed in the instant action is withdrawn. This action is not final due to new grounds of rejection made herein that were not necessitated by applicants' amendment of the claims in Paper No. 9.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 and 19-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in that the preamble of the claim does not necessarily match the end result of practicing the recited steps. The preamble of claim 1 recites "A method for identifying an agent that modulates NF-kB activity in transcription of a gene in a eukaryotic cell...". The body of the claim is directed towards an *in vitro* method for determining the level of deacetylated RelA in the presence of a test agent as compared to in the absence of the test agent. The claim further recites "...wherein detection of an increase of deacetylated RelA in the presence of the candidate agent...indicates that the agent inhibits activity of NF-kB in gene transcription." Taken with the preamble, this latter limitation appears to mean that the candidate

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agent **necessarily** is an inhibitor of NF- κ B activity in a cell when the recited method is an *in vitro* method. Agents identified as having an effect on a protein function *in vitro* are not necessarily going to have the same effect *in vivo* for various reasons (e.g. inability to enter the cell, degradation in the cell, multiple effects in the cell, etc.). It would be remedial to amend the claim language to clearly indicate that what is identified is an agent that affects deacetylation of RelA *in vitro* and which may be a candidate for affecting RelA activity *in vivo*.

Claim 6 is vague and indefinite in that it recites the limitation that the RelA used in the method of claim 1 is within a eukaryotic cell. This is mutually exclusive with the limitation in claim 1 that the candidate agent is contacted with RelA *in vitro*. Also, the recited limitation that the step of detecting deacetylated RelA is performed by detection of an increase in RelA binding to I κ B α does not mean that the agent will necessarily be one that affects deacetylation of RelA. For example, a compound that inhibits the dissociation of I κ B α from RelA would appear to be one that affects RelA acetylation in such a cellular assay.

Claim 7 is vague and indefinite in that the metes and bounds of the phrase "...comparing deacetylated RelA in the sample comprising the test substance to acetylation of RelA in a sample without the test substance; and determining whether the test substance provides for a level of deacetylated RelA greater than a level of deacetylated RelA in the absence of the test substance..." are unclear. The limitation of comparing deacetylated RelA in the sample in the presence of the test agent to "acetylation" of RelA in the absence of the agent makes it unclear if one is comparing the levels of deacetylated RelA in the presence/absence of the test agent, or if one is comparing in one case the level of deacetylated RelA to some other measurement for "acetylation" of RelA (e.g. level of acetylated RelA, rate of acetylation, etc.). Is this a

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comparison of apples to apples, or apples to oranges? Also, it is not clear what is intended by the term "provides" and what it implies about the function of the test agent. Upon reading the specification, it appears that what is intended is a measurement of the level of deacetylated RelA in the presence and absence of the test agent. It would be remedial to amend the claim language to indicate that (i) one compares the level of deacetylated RelA in the presence of the test agent to the level of deacetylated RelA in the absence of the agent, (ii) one determines if the level of deacetylated RelA is greater in the presence of the test agent, and (iii) wherein an increase in deacetylated RelA indicates the test substance inhibits NF-kB activity.

Claim 22 is vague and indefinite in that it recites a limitation of detecting an increase in deacetylated RelA in the presence of HDAC2. However, the rest of the claim is directed to HDAC3 and the specification does not appear to teach that HDAC2 is involved in the deacetylation of RelA. It would be remedial to delete the term "HDAC2" and substitute the term "HDAC3".

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gerald G. Leffers Jr.

Gerald G Leffers Jr.

Examiner

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Ggl

June 1, 2003

